

## EC – Declaration of Conformity

**Manufacturer:** Beltone A/S  
Lautrupbjerg 7  
DK-2750 Ballerup  
Denmark

**Conformity Assessment Procedure:** Annex II of Medical Device Directive (MDD) 93/42/EEC  
Annex III of Radio and Telecommunications Terminal  
Equipment (R&TTE) 1999/5/EC

**Identification of Notified Body (MDD):** DQS Medizinprodukte GmbH  
August-Schanz-Str. 21,  
D-60433 Frankfurt am Main, Germany  
Notified Body EC Code No. 0297

**Identification of EC-certificate (MDD):** DQS Certificate No. 283130 MR2

**Identification of the Device:** **Category:** Hearing Aid  
**Type:** In-The-Ear  
**Brand:** Beltone  
**Model:** Promise Family  
PSE1745-W, PSE1745-DW, PSE1745-DPW, PSE1745-PW  
PSE945-W, PSE945-DW, PSE-945-DPW, PSE945-PW

**Revision:** Report No. 208

**GMDN code:** 34672


**Declaration of Conformity expiry date:** 2016-12-31

**Classification of the Device (MDD):** Class IIa, Rule 9, MDD 93/42/EEC

**Applied standards and normative standards:**  
US: ANSI 63.19-2006  
MDD: IEC 60118-0:83+A1:94, IEC 60118-7:2005, IEC 60118-13:2004,  
ISO 10993-5:2009, ISO 10993-10:2010, ISO 14971:2007  
R&TTE: EN/(IEC) 60601-1-1:2001, EN/(IEC) 62311:2008 (Health & Safety)  
EN/(IEC) 60601-1-2:2001+A1, EN/(IEC) 301 489-17 2.1.1:2009 (EMC)  
EN/(IEC) 300 440-2 V1.3.1:2009 (Spectrum)

***We, the manufacturer hereby declare that the above-mentioned devices comply with the relevant provisions of the EU Council Directive 93/42/EEC (MDD) Annex I - Essential Requirements and the essential requirements and other relevant requirements of the R&TTE Directive 1999/5/EC and their relevant transpositions into national laws of the Member States in which the above mentioned medical devices are distributed.***

**Place and Date:** Ballerup, 30 August 2012

  
**Gian Carlo Sciuchetti**  
Senior Vice President  
Global Marketing  
GN ReSound A/S

  
**Lars Hagander**  
Vice President  
Corporate Quality  
GN ReSound A/S

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